

### **REMARKS/ARGUMENTS**

In response to the Final Office Action mailed November 4, 2003, Applicants propose to amend their application and request reconsideration in view of the amendments. In this amendment Claim 1 is proposed to be amended, Claims 2 and 6-22 were previously cancelled without prejudice and no claims have been added so that claims 1 and 3-5 are currently pending. No new matter has been introduced.

Claim 1 was rejected under 35 U.S.C. § 101. Applicants have amended the claim in accordance with the Examiner's suggestions. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1 and 3-5 were rejected as anticipated by U.S. Patent Number 6,547,814 to Edwin et al. (Edwin). This rejection is respectfully traversed.

Edwin discloses a method for selectively bonding layers of polymeric material to create endoluminal vascular devices. More particularly, Edwin discloses a method of bonding microporous polytetrafluoroethylene coverings over a stent scaffold in a manner which maintains unbonded regions to act as slip planes or pockets to accommodate planar movement of stent elements. The stent may be formed from nickel-titanium alloys. The stent comprises a plurality of struts arranged in a diamond pattern. The polymeric material may be attached to the stent via a number of ways, including a mechanical bond through the application of pressure or an adhesive. In one embodiment, successive tiers of diamond regions along the longitudinal axis of the device are alternately bonded and unbonded.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in amended independent claim 1, is directed to a stent. The stent comprises a plurality of hoops having a plurality of interconnected struts forming a substantially diamond shape configuration, a plurality of sinusoidal rings connecting adjacent hoops to one another, and proximal and distal attachment devices for securing a graft member to the stent. The stent has proximal and distal end hoops that are configured to have greater radial and longitudinal strength than the hoops therebetween. The proximal hoop is flared. The sinusoidal rings being formed from a plurality of alternating struts, wherein a junction of the alternating struts of the sinusoidal rings and a junction of interconnected struts of the plurality of hoops are a common junction. The proximal attachment device is positioned distal of the proximal open-end of the stent such that the proximal open end of the stent is exposed to the body vessel. Both the proximal and distal attachment devices comprise tabs formed from the joining of two struts and have at least two apertures therein.

Edwin fails to disclose a stent having a plurality of sinusoidal rings. Edwin fails to disclose a stent having attachment devices that comprise tabs with at least two apertures therein. Edwin cannot have attachment devices as such because in Edwin, the graft material is bonded to the stent structures. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1 and 3-5 were rejected as being unpatentable over U.S. Patent Number 6,231,598 to Berry et al. (Berry) in view of U.S. Patent Number 6,468,300 to Freidberg. Claims 1 and 3-5 were rejected as being unpatentable over Berry in view of U.S. Patent Number 6,355,057 to DeMarais et al. (DeMarais). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference

or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re Vaeck*, 947 F.2d, 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Berry discloses a radially expandable stent. The stent may be balloon expandable or self-expanding. The self-expanding stent may be formed from nickel-titanium alloys. In one embodiment, adjacent longitudinal segments are joined by flexible interconnection segments that permit the stent to bend laterally. The flexible interconnection segment is comprised of curvilinear struts that form a series of serpentine bends that distribute lateral bending forces. The flexible interconnection segments interconnect adjacent the longitudinal segments via at least one short interconnection strut.

Freidberg discloses a covered stent assembly comprising a tubular, expandable stent having a metallic framework covered with a cylinder of biocompatible, non-thrombogenic expandable material such as heterologous tissue, for example, bovine pericardial tissue. The stent extends about 1 mm beyond each of the cylinders to prevent prolapse of the tissue into the lumen of the stent when it is expanded. The cylinder may be secured to the metallic framework by any suitable means, for example, sutures.

DeMarais discloses an endoluminal prosthesis. The prosthesis comprises a liner supported by a frame. The frame comprises a series of independent ring frames affixed to the liner. Each of the ring frames is formed as a circumferential series of alternating large diamond shaped elements and small diamond elements. In one embodiment, the frame is disposed outside of the liner and in another embodiment, the liner is disposed outside of the frame. The liner may be attached to the frame utilizing a number of known techniques and devices, including sutures, adhesives, welding and weaving or braiding the frame elements into the liner. The liner is cut to match the pattern of the frames. In other words, the liner extends to the end of each diamond on each end of the frame.

Applicants respectfully submit that the prior art references, whether taken alone or in combination, fail to disclose or suggest all of the claim limitations. The references fail to disclose a stent having a plurality of hoops in a diamond configuration, the proximal hoop is flared, a plurality of sinusoidal rings between the hoops, and a distal and proximal attachment means formed as tabs at the junctions of struts, wherein the tabs have at least two apertures. In addition, the proximal end hoop is uncovered by graft material.

“When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.” In re Rouffet, 149 F.3d 1350, 1355 (Fed.Cir.1998). “Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.” In re Demiczak, 175 F.3d 994, 999 (Fed.Cir.1999). “One cannot use hindsight reconstruction to pick and choose

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among isolated disclosures in the prior art to deprecate the claimed invention.” In re Fine, 837 F.2d 1071, 1075 (Fed.Cir.1988).

Assuming arguendo that the references suggest all of the claimed features, Applicants respectfully submit that there is simply no motivation to combine the references without using the claimed invention. Accordingly, for the reasons given above, reconsideration and withdrawal of the rejections are respectfully requested.

The amendment raises no new issues and places the application in condition for allowance. Therefore, entry is proper and earnestly solicited.

Respectfully submitted,

By: \_\_\_\_\_



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